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REGULATORY GUIDE

Office of Nuclear Regulatory Research

Regulatory Guide 10.8
Guide for the Preparation of Applications for Medical Use Programs

(Task FC 415-4)

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1. INTRODUCTION

1.1 GENERAL

The Nuclear Regulatory Commission (NRC) regulates the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in 10 CFR Part 35, "Medical Use of Byproduct Material."

The NRC usually issues a single byproduct material license to cover an entire radioisotope program except teletherapy, nuclear-powered pacemakers, and irradiators. Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. A license applicant should carefully study this guide and all the regulations identified in Section 1.2 and should then complete the application form, NRC Form 313. The NRC may request additional information when necessary to provide reasonable assurance that the

applicant has established an adequate radiation protection program.

1.1.1 Purpose of Guide

This guide is designed to describe the type and extent of information needed by the NRC to evaluate an application for a medical use license and to describe the medical use byproduct material regulations. (Separate guidance is being developed to meet the specific needs of a teletherapy applicant. Draft Regulatory Guide FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs," has been issued for public comment.) This guide does not apply to academic programs that do not use byproduct material for medical use.

1.1.2 Purpose of Appendices to Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through R to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs. In the application, applicants may certify that they will follow model procedure (appropriate certification language is given at the beginning of each appendix) or may say that they have developed a procedure that is enclosed for review (appropriate reference language is given at the beginning of each appendix).

1.2 APPLICABLE REGULATIONS

In addition to 10 CFR Part 35, other regulations pertaining to the medical use of byproduct material are found in 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; and 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

This regulatory guide identifies the information needed to complete NRC Form 313 when applying for a license for a medical use program. The information collection requirements in NRC Form 313 have been cleared under OBM Clearance No. 3150-0120.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 20.1(c) of 10 CFR Part 20 states "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases 'of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guides 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," and 8.18, "Information Relevant to Ensuring That Occupational

Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," provide the NRC staff position on this important subject. Applicants should consider the ALARA philosophy as described in Regulatory Guides 8.10 and 8.18 in developing plans for work with licensed radioactive materials.

1.3.1 General ALARA Considerations

Each individual who is authorized to use byproduct material should provide appropriate instruction to all individuals who work with or in the vicinity of byproduct material and should ensure that the facility and equipment are adequate for safe use. NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities," provides information on training programs for use by medical use licensees. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Office (RSO).

1.3.2 ALARA in Medical Institutions

Each medical licensee must have a formal ALARA program (see § 35.20 of 10 CFR Part 35). The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of byproduct material is required by § 35.22 to reyiew uses for safety and ALARA considerations. (See Section 1.4.2 of this guide).

The Committee, the RSO, and management should audit the byproduct material program to ensure the continued safe use of byproduct material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

A model ALARA management program is contained in Appendix G to this guide. Several other NRC publications contain background information on the ALARA philosophy and its application in the medical envirohment. For example, Regulatory Guide 8.18 and NUREG-02&7, "Principles and' Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably

Achievable," contain information, methods, and references useful in establishing radiation safety programs to maintain exposures ALARA is medical institutions. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

1.4 TYPES OF LICENSES

The NRC issues three types of licenses for the use of byproduct material in the practice of medicine. They are described below. This guide is only for persons who want to apply for a specific medical use license. However, persons who are applying for other types of licenses may find the information in this guide useful in designing their radiation safety program.

1.4.1 General License

Section 31.11 of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving medical use (that is, not involving administration to humans). Section 31.11 explains the requirements for using materials listed in that section. If the general license alone meets the applicant's needs, only Form NRC-483, "Registration Certificate--In Vitro Testing with Byproduct Material under General License," need to be filed. Medical use licensees do not need to file the form (see paragraph 31.11(b)).

If you need more than 200 microcuries of photon-emitting § 31.11 materials, you may request an increased ,inventory limit as a separate line item on your NRC Form 313 application. Licensees generally request 3 millicuries. The use of materials listed in § 31.11 within the inventory limits of that section will only be subject to the requirements of that section and not subject to the requirements of Parts 19, 20, 21, and 35 except as provided in § 31.11. If you request an increased inventory limit, you will be subject to the requirements of those parts., including the requirements regarding waste disposal.

1.4.2 Specific License

Specific licenses for physicians in private practice are generally limited to physicians who are located in private offices and not on hospital premises. A Radiation Safety Committee is not required. Methods of use that require hospitalization of the patient are not permitted.

Specific licenses are also issued to medical institutions. A medical institution is an organization in which several medical disciplines are practiced. These licenses authorize byproduct material for medical uses by physicians named on the institution's license. The regulations in § 35.22 of 10 CFR Part 35 require an institutional licensee to have a Radiation Safety Committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. The physicians named on the institution's license conduct their programs with the approval of the Radiation Safety Committee.

A specific license may also be issued for a mobile nuclear medicine service (see § 35.29 of Part 35). Both private practitioners and institutions may apply for authorization to use byproduct material in a mobile service.

1.4.3 Specific License of Broad Scope

Some medical institutions provide patient care and conduct research programs that use radioisotopes for in vitro, animal, and medical procedures. In these cases, the NRC may issue a specific license of broad scope as discussed in 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material." Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of byproduct material for unspecified uses, are issued to institutions that (1) have had previous experience operating under a specific institutional license of limited scope and (2) are engaged in medical research as well as routine diagnosis and therapy using radioisotopes.

Such programs operate under the supervision of the Radiation Safety Committee. A broad scope license allows the Radiation Safety

Committee to review proposed methods of use and to permit individuals to use material under the provisions of the broad scope license. An applicant for a broad scope license must show that appropriate personnel, equipment, and facilities are available. Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and methods of use are authorized by the institution's Radiation Safety Committee. This type of license is not appropriate for most institutions performing routine procedures with byproduct material.

Institutions may also apply for a broad scope license that combines features of the specific license and the specific license of broad scope discussed above. It authorizes medical uses as described in Part 35 and authorizes the Committee to review and approve in vitro animal research uses. This type of license is not appropriate for most institutions performing routine medical procedures with byproduct material.

2. FILING AN APPLICATION

You should apply for a license by completing NRC Form 313 (see Exhibit 1). You should complete Items 1 through 2, 12, 13, and 14 on the form itself. For Items 5 through 11, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the items number of the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

You should complete all items in the application in enough detail for the NRC to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

Please note that license applications are available for review by the general public in the NRC Public Document Rooms. Do not submit proprietary -information unless absolutely necessary. If submittal of such information is necessary, follow the procedure in § 2.790 of 10 CFR Part 2. Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

You should file your application in duplicate. Retain one copy for yourself because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations.

If you wish to possess or use licensed material on Federal property or in any State subject to NRC jurisdiction, you should file your application with the NRC Regional Office for the State in which the material will be possessed or used. The exceptions to the above are the United States Air Force and Navy and persons wishing to distribute exempt material under 10 CFR Part 32, Subpart A, who should file

their applications directly with the U.S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Washington, DC 20555.

Many States have entered into agreements with the NRC that give them the authority to license radioactive materials used or possessed within their borders. These States are called Agreement States. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the Material Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or from NRC's Regional Offices, whose addresses are listed below. If you are a non-Federal organization that wishes to possess or use licensed material in one of these Agreement States, your application should be filed with the State's radiation control program and not with the NRC.

If you are located in Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont, send your applications to the U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 631 Park Avenue, King of Prussia, PA 19406.

If you are located in Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, or West Virginia, send your applications to the U.S. Nuclear Regulatory Commission, Region II, Material Radiation Protection Section, 101 Marietta Street, Suite 2900, Atlanta, GA 30323.

If you are located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, send your applications to the U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, IL 60137.

If you are located in Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, or Wyoming, send your applications to the U.S. Nuclear Regulatory Commission, Region IV; Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011.

If you are located in Alaska, Arizona, California, Hawaii, Nevada, Oregon, Washington, or U.S. territories and possession in the Pacific, send your applications to the U.S. Nuclear Regulatory Commission, Region V, Material Radiation Protection Section, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

3. CONTENTS OF APPLICATION

This portion of the guide explains, item by item, the information requested on NRC Form 313 (Exhibit 1). The appendices to this guide serve several different purposes, i.e., to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application form, or to provide an outline the applicant may use to develop a procedure for review by the NRC staff. The exhibits following the appendices include copies of the application form (NRC Form 313, Exhibit 1); Supplements A and B (Exhibits 2 and 3) that may be used to document training and experience; and two logs to document training, the Resident's Support

Technology Training Task Log (Exhibit 4) and Resident's Clinical Procedures Training Log (Exhibit 5). Exhibits 4 and 5 may be used as worksheets when preparing Supplements A and B.

If you have specific questions after careful review of this guide, contact the NRC material licensing staff at the appropriate address as specified in Section 2 of this guide.

Item 1 - LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check subitem C.

Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 3.

Item 3 - LOCATIONS OF USE

You should specify each location of use by the street address, city, and State or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) to allow us to easily locate your facilities. A post office box address is not acceptable. If byproduct material is to be used at more than one location, you must give the specific address of each location. In Items 5 through 11 of the application, describe the intended use and the facilities and equipment at each location.

If you are applying for a license for a mobile nuclear medicine service, specify so and list the name and location of each client.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer questions about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the NRC if the individual assigned to this function changes. Notification of a contact change is for information only .and would not be considered an application for a license amendment.

Item 5 - RADIOACTIVE MATERIAL and Item 6 - PURPOSE

Part 35 divides byproduct material for medical use into six types of use. Using the table format of Table 1 as a guide,. you may indicate only the types of use you want and the maximum amount. You may say As needed" in the "Amount" column as shown. For § 35.400 implant material, express the total amount in millicuries (mCi). If you plant to have an eye applicator, list it as a separate line item and note its total activity in mCi.

Table 1

	Byproduct Material	**Amount**		**Purpose**
5.a	Material in § 35.100	As needed	6.a	Medical use
5.b	Material in § 35.200	As needed	6.b	Medical use
5.c	Material in § 35.300	As needed	6.c	Medical use
5.d	Implant Material in § 35.400	____ mCi	6.d	Medical use
5.e	Eye applicator in § 35.400	____ mCi	6.e	Medical use
5.f	Material in § 35.500	As needed	6.f	Medical use

(Note: Broad scope medical use applicants may request "Any byproduct material with atomic numbers 3 through 83 for medical use.,")

If you need other items (for example, more byproduct material for in vitro testing than is allowed under § 31.11, depleted uranium for linear accelerator shielding, a survey meter calibration source, a teletherapy dosimetry system constancy check source, or material for in vitro, animal, or human studies, or authorization to participate in a protocol approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration), make a separate line entry for each item. (Do, not list sources that are authorized in § 35.58.) Number each line entry consecutively following the Part 35 material. Each line entry must identify the radionuclide, the physical form, maximum amount of hand expressed in mCi, and the purpose for which the material will be used. If you do not want all the material listed in a Part 35 section, you must identify, line by line, the material that you do want from the section.

Item 7 - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS--THEIR TRAINING AND EXPERIENCE

Responsible individuals are the authorized users, the RSO, and for teletherapy the teletherapy physicist. Paragraph 30.33(a)(3) of 10 CFR Part 30 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subpart J of Part 35 provides specific criteria for acceptable training and experience for authorized users for medical use, for the RSO, and for the teletherapy physicist. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate,

2. Prescription of the radiation dosage or dose and how it is to be administered,

3. Actual use of, or direction of technologists or other paramedical personnel in the use of, byproduct material, and

4. Interpretation of results of diagnostic procedures and evaluation of results of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the supervision of an authorized user. 'Technologists or other personnel may use byproduct material under an authorized user's supervision when permitted under applicable Federal, State, or local laws. Supervision is defined in § 35.25.

For in vitro and animal research or other uses that do not involve the intentional exposure of humans, the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the byproduct material for the requested use. Note which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the byproduct material by technologists or other individuals for the requested use.

7.1 Authorized Users for Medical Use

1. Make a separate attachment for the RSO and each authorized user. Number the attachments "ATT 7.1.1," "ATT 7.1.2," etc. Type the full name of the individual and note, by reference to Items 5.a, 5.b, etc., which proposed uses are requested for the individual.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you only need to submit the previous license number (if issued by AEC or NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an authorized user.

3. If a physician is certified by an organization listed in the appropriate section of Subpart 3 of 10 CFR Part 35, submit Supplement A (see Exhibit 2) with Items 1, 2, and 3 completed. A physician certified as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) should submit a copy of the certificate and evidence of specialization in radiation therapy.

4. Physicians not previously authorized by AEC or NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B (see Exhibits 2 and 3). This documentation will be reviewed on a case-by-case basis. If the training and experience does not appear to meet the Subpart J standards, the NRC will request the assistance of its Advisory Committee on the Medical Uses of Isotopes.

5. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. Subpart J may be used as a guide. The criteria may include a provision that allows the applicant's Radiation Safety Committee to grant case-by-case exceptions.

7.2 Authorized Users for Nonmedical Use

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person 5 training and experience using Supplement A (Exhibit 2). If the individual was already identified in Item 7.1, no additional attachment is needed here.

7.3 Radiation Safety Officer

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A (see Exhibit 2). The RSO should be a full-time employee of the licensee. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

Items 8 through 11

Your responses to these items should consist of one sentence that says that you will follow the model procedure in Appendix__ in Regulatory Guide 10.8, or that you have enclosed your procedure for review, or simply the notation "NA" for "not applicable." Follow the instructions on the Applicability Table, Table 2, to determine whether you must provide information or may simply respond "NA" to each item that follows. Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your short sentence or NA responses to Items 8 through 11 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to identify responsible individuals, equipment by name or model, room numbers, or other site-specific information, there is no need to submit that procedure for review.

Table 2

APPLICABILITY TABLE

To determine those items to which you must respond, "highlight" the columns under the categories of material you requested in Item 5. If any "4" beside an item is highlighted, you must provide information in response to the item. If only the letters "NA" (not applicable) are highlighted, you may respond "NA" in your application.

		Material in 10 CFR Sections						
Item	**Topic**	**35.100**	**35.200**	**35.300**	**35.400**	**35.500**	**Other**	**App.**
8.1	Training program	✔	✔	✔	✔	✔	NA	A
8.2	Other training program	NA	NA	NA	NA	NA	✔	-
9.1	Annotated drawing	✔	✔	✔	✔	✔	✔	Exh. 1
9.2	Survey instrument calibration	✔	✔	✔	✔	✔	✔	B
9.3	Dose calibrater calibration	✔	✔	✔	NA	NA	NA	C
9.4	Personnel monitor program	✔	✔	✔	✔	NA	✔	D

9.5	Imaging equipment QA	(See special instruction 9.5 in the text)						E
9.6	Other equipment facilities	NA	NA	NA	NA	NA	✓	-
10.1	Radiation Safety Committee/Radiation Safety Officer	(See special instruction 10.1 in the text)						F
10.2	ALARA program	(See special instruction 10.2 in the text)						G
10.3	Leak test	✓	✓	✓	✓	✓	NA	H
10.4	Safe use of radiopharmaceuticals	✓	✓	✓	NA	NA	NA	I
10.5	Spill procedures	✓	✓	✓	NA	NA	NA	J
10.6	Ordering and receiving	✓	✓	✓	✓	✓	✓	K
10.7	Opening packages	✓	✓	✓	✓	✓	✓	L
10.8	Unit dose records	✓	✓	✓	NA	NA	NA	M
10.9	Multidose vial records	✓	✓	✓	NA	NA	NA	M
10.10	Mo-99 concentration records	NA	✓	NA	NA	NA	NA	M
10.11	Implant source use records	NA	NA	NA	✓	NA	NA	M
10.12	Area survey procedures	✓	✓	✓	✓	NA	✓	N
10.13	Air concentration control	NA	✓	NA	NA	NA	NA	O
10.14	Radiopharmaceutical therapy	NA	NA	✓	NA	NA	NA	P
10.15	Implant therapy	NA	NA	NA	✓	NA	NA	Q
10.16	Other safety procedures	NA	NA	NA	NA	NA	✓	-
11.1	Waste disposal	✓	✓	✓	✓	✓	NA	R
11.2	Other waste disposal	NA	NA	NA	NA	NA	✓	-

Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.1 Training Program

Describe your training program for individuals who work with or in the vicinity of radioactive material described in Part 35. See Appendix A of this guide.

8.2 Other Training Program

Describe your training program for individuals who handle radioactive material other than the Part 35 material that you listed in Item 5 of this application. Append it as ATT 8.2.

Item 9 - FACILITIES AND EQUIPMENT

9.1 Annotated Drawing

Submit an annotated drawing of the room or rooms and adjacent areas where byproduct material will be used. Append it as ATT 9.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.

2. The direction of north.

3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway).

4. Any shielding available.

5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

See Exhibit 6 for an example.

9.2 Survey Instrument Calibration

Submit your procedure for calibrating survey instruments. See Appendix B.

9.3 Dose Calibrator Calibration

Submit your procedure for calibrating the dose calibrator. See Appendix C.

9.4 Personnel Monitor Program

Describe your personnel occupational exposure monitor program. See Appendix D of this guide.

9.5 Imaging Equipment

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. See Appendix E. If you are not going to provide mobile nuclear medicine service, say "NA."

9.6 Other Equipment and Facilities

Describe other equipment and facilities available for the use and storage of material described in Item 5 of this application other than material described in Part 35. Append it as ATT 9.6.

Item 10 - RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by each medical institution licensee (see § 35.22) unless the application is only for devices listed in § 35.500 (such institutions will be exempted by license condition). If you are not an institution, you only need to submit the Radiation Safety Officer delegation of authority. See Appendix F.

10.2 ALARA Program

Submit your ALARA program. Each medical licensee must have an ALARA program (see § 35.20) unless the application is only for devices listed in §35.500 (such institutions will be exempt by license condition). If you are only applying for devices in § 35.500, say "NA." Otherwise, see Appendix G.

10.3 Leak Test

Submit your procedure for leak-testing sealed sources. See Appendix H.

10.4 Safe Use of Radiopharmaceuticals

Submit a copy of your rules for the safe use of radiopharmaceuticals. See Appendix I.

10.5 Spill Procedures

Submit a copy of your spill procedures. See Appendix 3.

10.6 Ordering and Receiving

Submit a copy of your procedure for ordering and receiving radioactive material. See Appendix K.

10.7 Opening Packages

Submit your procedure for opening packages that contain radioactive material. See Appendix L.

10.8 Unit Dosage Records

Submit your procedure for keeping records of unit dosage use. See Appendix M.1.

10.9 Multidose Vial Records

Submit your procedure for keeping records of multidose vial use. See Appendix M.2.

10.10 Molybdenum Concentration Records

Submit your procedure for measuring and recording molybdenum concentration. See Appendix M.3.

10.11 Implant Source Use Records

Submit your procedure for keeping an inventory of implant sources. See Appendix M.4.-

10.12 Area Survey Procedures

Submit your area survey procedures. See Appendix N.

10.13 Air Concentration Control

1. Submit your procedure for estimating worker dose from submersion in noble gases. See Appendix 0.

2. Submit your procedure for estimating worker dose from aerosol concentrations. See Appendix 0.

3. Submit your procedure for estimating aerosol-and gas concentration in effluents. See Appendix 0.

4. Submit your procedure for calculating spilled gas clearance tim,es. See Appendix 0.

10.14 Radiopharmaceutical Therapy

Submit your procedure for radiation safety during radiopharmaceutical therapy. See Appendix P.

10.15 Implant Therapy

Submit your procedure for radiation safety during implant therapy. See Appendix Q.

10.16 Other Safety Procedures

Submit safety procedures that will be followed by individuals who handle radioactive material described in Item 5 of this application other than material described in Part 35. Append them as ATT 10.16.

Item 11 - WASTE MANAGEMENT

11.1 Waste Disposal

Submit your procedures for waste disposal. See Appendix R.

11.2 Other Waste Disposal

Submit waste disposal procedures that will be followed for radioactive materials described in Item 5 of this application other than material described in Part 35. Append them as ATT 11.2. (If they are the same as the procedures submitted in Item 11.1, say "See Item 11.1.")

Item 12 - LICENSE FEES

An application fee paid in full is required by paragraph 170.12(a) of 10 CFR Part 170 for most types of licenses, including applications for license amendments and renewals. You should-refer to § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of the fee that must accompany your application. An application received without a fee or with an inadequate fee may be returned to you. All application fees may be charged irrespective of the NRC's disposition of the application or your withdrawal of the application.

Item 13 - CERTIFICATION

If the application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

BEFORE SUBMITTING IT, REVIEW YOUR APPLICATION TO BE SURE YOU HAVE RESPONDED TO EACH ITEM AND TO BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED HAS AN ATTACHMENT NUMBER AND IS DATED.

Item 14 - VOLUNTARY ECONOMIC DATA

The Regulatory Flexibility Act of 1980 requires Federal agencies to consider the effects of their rules on small businesses and other small entities. In order for the NRC to maintain an up-to-date data base of its licensees, four categories of economic information are sought from applicants. This economic data will be used by the NRC in preparing regulatory analyses that contain, among other things, the anticipated.economic burden a proposed rulemaking action will have on affected licensees. To the extent that it is possible and consistent with public health and safety, the NRC will consider the economic -burden in light of the size of the entities affected by the rule in an attempt to mitigate the potential for a significant economic impact on a substantial number of small entities.

14.a Annual Receipts

Guidance for determining the approximate box in 14.a, Annual Receipts:[1]

1. Holders of One NRC License. If your organization (named on the license or application) holds one NRC license and operates from one address, check the box that most closely approximates your annual receipts; in the case of hospitals, academic institutions, or other entities that do not operate on the, basis of receipts, check the box that most closely approximates the annual ope,ra'ting budget of your organization.

2. Holders of Multiple NRC Licenses Issued for One Address. If your organization (named on the license or application) holds multiple NRC licenses, all of which are issued to the same address, check the box that most closely approximates the annual receipts or annual operating budget for your entire organization, regardless of the number of NRC licenses possessed at that single address.

3. Holders bf Multiple NRC Licenses at Multiple Addresses. If your organization (named on the license or application) holds multiple, NRC licenses -at multiple addresses, check the box that most closely approximates the annual recejpts or annual operating budget for the operations conducted at the address on'this license or application and not for the entire corporate entity.

14.b Number of Employees

The number of employees reported should reflect all employees for the organization at the address listed on the license or application, excluding outside 'contractors. The number of employees reported should not be that of a single department or division within the organization.

14.c Number of Beds (Hospitals Only)

Enter the total number of beds in the hospital, excluding bassinets and nursing-home-type units.

14.d Would You Be Willing To Furnish Cost Information on the Economic Impact of Current Regulations or any Future Proposed NRC Regulations That May Affect You?

Indicate if you would be willing to furnish additional economic data to the NRC that would help the NRC evaluate the economic impact of a rule on affected licensees.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program, changing the Radiation Safety Officer or teletherapy physicist, or adding to the staff of authorized users. See § 35.13 for the specific requirements. An application for an amendment must be filed in duplicate either on NRC Form 313 or as a letter and must be signed as described in Item 13. If the amendment application is the first one submitted after the effective date of the revision of 10 CFR Part 35 (April 1, 1987), the NRC will use this opportunity to list the Radiation Safety Officer and teletherapy physicist on the license. The teletherapy physicist's credentials must be submitted as part of the amendment application.

5. RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30. The application for renewal must be filed in duplicate on NRC Form 313. The application for renewal may reference attachments that were previously submitted. For example, "See ATT 10.7 dated November 14, 1985."

6. IMPLEMENTATION

The purpose of this section is to provide information to you about the NRC staff's plans for using this regulatory guide and how these plans affect you.

The guide was distributed for comment to encourage public participation in its development (Task FC 415-4, August 1985). This final Revision 2 represents the staff position of the NRC, which incorporates the public comments that were received on the draft guide.

The draft guide and final guide differ. If your license was issued or amended based on recommendations in the draft guide that are more restrictive than those in the final guide, you may choose to request an amendment to your license to incorporate the less restrictive guidance.

In cases where the final guide is more restrictive than the draft guide, licensing actions already completed will not be affected because all required regulatory findings have been made. However, the more restrictive recommendations in the final guide reflect items identified by the NRC staff as important to health and safety. Discrepancies may be addressed for effective licenses by license amendment or rule change. In unusual cases in which immediate action is required, you would be contacted directly by the NRC.

The information in this regulatory guide is guidance, not requirements. The NRC reviews each application to ensure that users of byproduct material are capable of complying with NRC's regulations. This guide provides one set of methods approved by the NRC for meeting the regulations.

APPENDICES
Part 1 - MODEL PROCEDURES THAT APPLICANTS MAY USE TO PLAN RADIATION SAFETY PROGRAMS

APPENDIX A: Model Training Program

(See §§ 9.12 and 35.21)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.
10. Question and answer period.

APPENDIX B: Model Procedure for Calibrating Survey Instruments

(See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.
3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.
8. Three kinds of scales are frequently used on survey meters:
   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point

on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
    a. The owner or user of the instrument;
    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;
    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
    f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);
    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
    h. The apparent exposure rate from the check source; and
    i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
    a. The source that was used to calibrate the instrument;
    b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
    c. For each scale or decade, one of the following as appropriate:
        (1) The average correction factor,
        (2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or
        (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
    d. The angle between the radiation flux and the detector during the calibration; and
    e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker. See Exhibit 7 for a form you may want to use.

APPENDIX C: Model Procedure for Calibrating Dose Calibrator

(See § 35.50.)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2."

If you develop your own dose calibrator calibration procedure for review, you should carefully review § 35.50 and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)
   a. Constancy at least once each day prior to assay of patient dosages (±5 percent).
   b. Linearity at installation and at least quarterly thereafter (±5 percent).
   c. Geometry dependence at installation (±5 percent).
   d. Accuracy at installation and at least annually thereafter (±5 percent).
2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, [2] or Ra-226 [2] using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:
   a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
   b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
   c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
   d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
   e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit 8). This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more than $\pm$0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.
i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
b. Steps c through e below must be completed within 6 minutes.
c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
e. Continue for all sleeves.
f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
g. Plot the data using the equivalent decay time associated with each sleeve.
h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.
i. If the worst deviation is more than $\pm$0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).
c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
d. Repeat the process until you have assayed a 2.0-cc volume.
e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."
f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it

will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9). Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

See Exhibits 8 and 9 for some forms you may want to use.

APPENDIX D: Model Personnel External Exposure Monitoring Program

(See § 20.101.)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of § 20.101. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4," and append your monitoring program.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.
4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.
5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX E: Model Procedure for Checking Equipment Used in Mobile Nuclear Medicine Service

(See §§ 35.29 and 35.80.)

The NRC normally limits its review of equipment quality assurance programs to those programs developed for radiation safety equipment. However, when delicate imaging equipment is transported from one location of use to another, e.g., by a mobile nuclear medicine service, it is reasonable to assume that it may suffer damage in transit. Therefore, the NRC requires that mobile nuclear medicine services have an imaging equipment quality assurance program to ensure that the use of byproduct material will not be inimical to the public health and safety. Mobile nuclear medicine services should also check ventilation equipment if gases or aerosols will be used.

You may use the following procedure to ensure the proper operation of imaging equipment that has been transported. If you follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix E to Regulatory Guide 10.8, Revision 2."

If you want to develop your own procedure for review, you should consider for inclusion all the features in the model procedure and the procedure recommended by the manufacturer and carefully review the requirements of §§ 35.29 and 35.80. Say on your application, "We have developed a procedure for ensuring equipment performance for your review that is appended as ATT. 9.5," and append your imaging equipment quality assurance procedure.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source at each location of use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering byproduct material:
   a. Peak each camera according to the manufacturer's instructions.
   b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.
   c. Do not administer material until an authorized user or a designated technologist approves the camera for use.
   d. You do not have to make a permanent record of these daily checks.
2. Perform the following checks weekly:
   a. With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH) or resolution-quadrant phantom with the flood field as a source.
   b. If a PLES or bar phantom is used, rotate it 90° so that the camera is tested for both vertical and horizontal geometric linearity.
   c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each

quadrant of the crystal.

d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.
e. Retain the images for 2 years.

3. Perform the following safety checks after repairs and quarterly:
   a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.
   b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.
4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for 2 years.

Ventilation

If gases or aerosols will be used, check the ventilation supply, exhaust vents, and collection devices for operation with tissue paper or a velometer. There is no need to keep a record of these checks.

APPENDIX F: Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority

(See §§ 35.21, 35.22, and 35.23.)

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of §§ 35.22. Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies,

and procedures;
2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
4. Establish a table of investigational levels for individual occupational radiation exposures; and
5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;
2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;
4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19;
7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and
10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.
2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)
3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be

present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: All Employees
From: Chief Executive Officer
Subject: Delegation of Authority

_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

APPENDIX G: Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA

(See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

_____

(Licensee's Name)

_____

(Date)

1. Management Commitment
   a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.
2. Radiation Safety Committee
   a. Review of Proposed Users and Uses
      (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
      (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.
      (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
   b. Delegation of Authority

      (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)
      (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
      (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
   c. Review of ALARA Program
      (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to

implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).[3]

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized

Users

a. New Methods of Use Involving Potential Radiation Doses
   (1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
   (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals
   (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
   (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses
   a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
   b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1. In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official[5]

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____

Signature

_____

Name (print or type)

_____

Title

Table 1

		Investigational Levels (mrems per calendar quarter)	
		Level I	**Level II**
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body[4]	750	2250

APPENDIX H: Model Procedure for Leak-Testing Sealed Sources

(See § 35.59.)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was

published in Appendix H to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.59. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
   c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.
   d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
4. The samples will be analyzed as follows:
   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
   e. Continue the same analysis procedure for all wipe samples.
   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b)

of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)

g. Sign and date the list of sources, data, and calculations.

APPENDIX I: Model Rules for Safe Use of Radiopharmaceuticals

(See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of

Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J: Model Spill Procedures

(See § 35.21.)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 10.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and

shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparision of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 FR 1092.
2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.
3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30,

paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 FR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1
Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
"Radioactive Material" labeling tape
1 china pencil or marking pen
3 prestrung "Radioactive Material" labeling tags

Supplies for 10 contamination wipe samples
Instructions for "Emergency Procedures"
Clipboard with one copy of Radioactive Spill Report Form
Pencil

Forms

You may want to use Exhibit 10, Radioactive Spill Report, and Exhibit 11, Radioactive Spill Contamination Survey Forms.

APPENDIX K: Model Guidance for Ordering and Receiving Radioactive Material

(See §§ 30.51 and 20.205.)

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
   a. For routinely used materials
      (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.
      (2) The above records will be checked to confirm that material received was ordered through proper channels.
   b. For occasionally used materials (e.g., therapeutic dosages)
      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
      (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.
4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room ____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____ , at extension ___.

	Name	Home	Telephone
Radiation Safety Officer:			
Chief of Nuclear Medicine:			
Chief Nuclear Medicine Technologist:			
Nuclear Medicine Technologist on call (call page operator at extension ___)			
Nuclear Medicine Physician on call (call page operator at extension ___)			

APPENDIX L: Model Procedure for Safely Opening Packages Containing Radioactive Material

(See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm*.
2. For packages received under the specific license, the following procedure for opening each package will be followed:
   a. Put on gloves to prevent hand contamination.
   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))
   d. Open the package with the following precautionary steps:
      (1) Remove the packing slip.
      (2) Open the outer package following the supplier's instructions, if provided.
      (3) Open the inner package and verify that the contents agree with the packing slip.
      (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
      (5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.
f. Check the user request to ensure that the material received is the material that was ordered.
g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
   (1) If contaminated, treat this material as radioactive waste.
   (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:
   a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
   b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

APPENDIX M: Records of Byproduct Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures.

Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the

features in the model procedure and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8," and append your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Measured activity in millicuries or microcuries and date and time of measurement,
   c. Patient name and identification number if one has been assigned;
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

See Exhibit 13 for a Unit Dosage Receipt and Use Log Form you may want to use.

M.2 Records of Multidose Vial Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9," and append your multidose vial record procedure.

MODEL PROCEDURE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3 Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. Supplier or kit manufacturer;
6. If administered,
    a. Prescribed dosage (unless already recorded in clinical procedure manual),
    b. Date and time dosage was drawn and measured,
    c. Calculated volume that is needed for the prescribed dosage,
    d. Measured activity in millicuries or microcuries,
    e. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

See Exhibit 14 for a Multidose Vial Preparation and Use Log Form you may want to use.

M.3 Measuring and Recording Molybdenum Concentration (§ 35.204)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported under paragraph 21.21(b) of 10 CFR Part 21.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.204. Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as ATT 10.10," and append your

procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;
2. Date and time of elution;
3. Measured Mo-99 activity in microcuries;
4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;
5. Measured Tc-99m activity in millicuries;
6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with paragraph 21.21(b) of 10 CFR Part 21, the licensee must notify the NRC if a leaking generator is detected.) [The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.]
7. Initials of the person who made the record.

M.4 Keeping an Inventory of Implant Sources (§§ 30.51, 35.21, 35.406)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.406. Say on your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as ATT 10.11," and append your procedure for keeping an inventory and use record for implant sources.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.
2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's

name, and the time and date they were removed from storage; initial the record.
6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.
7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

See Exhibit 15 for a sample form you may want to use.

APPENDIX N: Model Procedure for Area Surveys

(See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas
   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.
2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.
c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm* of removable contamination (200 dpm/100 cm* for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.
3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:
   a. The date, area surveyed, and equipment used.
   b. The name or initials of the person who made the survey.
   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)
   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm*, as appropriate.
   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.
2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1
Recommended Action Levels in dpm/100 cm* for Surface Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125,I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX O: Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations

(See §§ 20.103, 20.106, 20.201, 35.90, and 35.205.)

WORKER DOSE FROM NOBLE GASES (Item 10.13.1)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix O.3 to Regulatory Guide 10.8, Revision 2.

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC review during inspections.) If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item 10.13.1 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as ATT 10.13.1," and append your procedure for monitoring worker dose from noble gases.

WORKER DOSE FROM AEROSOLS (Item 10.13.2)

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturer's instructions for checking for accuracy and constancy, you may respond to Item 10.13.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC review during inspections.) If you will follow

the model procedure below for calculating worker dose from aerosols, you may respond to Item 10.13.2 by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to aerosol concentrations that is appended as ATT 10.13.2," and append your procedure for monitoring worker dose from aerosols.

O.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:
   a. Estimated number of studies per week;
   b. Activity to be administered per study;
   c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);
   d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);
   e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);
   f. Measured airflow exhaust at the storage site (e.g., a fume hood); and
   g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1 x 10-* *Ci/ml in restricted areas and 3 x 10-* *Ci/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 4 x 10-* *Ci/ml in restricted areas and 1 x 10-* *Ci/ml in unrestricted areas. For other gases or aerosols, see Appendix B to 10 CFR Part 20.
2. The following calculations must be made:
   a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
   b. The estimated average concentration in restricted areas.
      (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.
      (2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

O.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total

volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.

2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

O.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 10.13.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Appendix B to 10 CFR Part 20.If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item 10.13.3 by saying, "We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for NRC

review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond to Item 10.13.3 by saying, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix 0.2 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information

and carefully review the requirements of §§ 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as ATT 10.13.3," and append your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME (Item 10.13.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix O.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 10.13.4 by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix O.4 to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of § 35.205. Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.13.4," and append your procedure.

O.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:
   a. A, the highest activity of gas in a single container, in microcuries;
   b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
   c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
   d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1 x 10-* *Ci/ml in restricted areas and 3 x 10-* *Ci/ml in unrestricted areas. For other gases, see Appendix B to 10 CFR Part 20; and
   e. V, the volume of the room in milliliters.
2. For each room make the following calculations:
   a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
   b. The evacuation time $t = \frac{-V}{Q} \times \ln (C \times V / A)$

APPENDIX P: Model Procedure for Radiation Safety During Iodine Therapy Over 30 Millicuries

(See §§ 35.300, 35.75, and 20.105.)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, and 35.300. Say on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14," and append your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
2. Prepare the room for the procedure as follows:
   a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
   b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.
   c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
      (1) Containers should be unbreakable and closable
      (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
      (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
      (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)
      (5) Supply a wide-mouth antisplash funnel.
   d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.
5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131,

Phosphorus-32, or Gold-198" (Exhibit 17), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
7. Only those persons needed for medical, safety, or training purposes should be present during the administration.
8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.
10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see § 35.75). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
    a. Remove all absorbent paper, and place it in the appropriate container.
    b. Transfer all containers to a decay-in-storage or decontamination area.
    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm*.
    d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 18, "Radiation Safety Checklist for Iodine Therapy over 30 Millicuries," may also be helpful to you.

APPENDIX Q: Model Procedure for Radiation Safety During Implant Therapy

(See §§ 35.75, 35.404, and 35.406.)

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, 35.404, and 35.406. Say on your application, "We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 10.15," and append your procedure.

You may find a checklist to be helpful, such as Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy."

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in paragraph 20.105(b) of 10 CFR Part 20.
2. Supply the nurses with film badges, TLDs, or pocket ionization chambers.
3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Temporary Implant Sources," Exhibit 20, or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.
8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.
9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

You may want to use the sample forms in Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy," Exhibit 20, "Nursing Instructions for Patients Treated with Temporary Implant Sources," and Exhibit 21, "Sample Cesium Implant Source Log."

APPENDIX R: Model Procedure for Waste Disposal

(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide,

estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.
4. Prior to disposal as in-house waste, monitor each container as follows:
   a. Check your radiation detection survey meter for proper operation;
   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;
   c. Remove any shielding from around the container;
   d. Monitor all surfaces of each individual container;
   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.
   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

Part 2 - ADDITIONAL INFORMATION FOR MANAGING RADIATION SAFETY PROGRAMS FOR MEDICAL USE LICENSEES

APPENDIX S: Regulatory Requirements

The following documents provide licensees with a summary of the information considered by the Commission when preparing the revision of 10 CFR Part 35.

Federal Register **Volume 51, No. 200 Thursday, October 16, 1986** **Rule and Regulations** **Title 10 Chapter 1, Code of Federal Regulations-Energy**	
Document Title	**Page No.**

	(Click to View .GIF File)
Commission Notices - Policy Statements	1
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10 CFR Parts 30, 31, 32, 35 and 40 - Medical Use of Byproduct Material	
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APPENDIX T: Considerations in Making Radiation Safety Program Changes

(See § 35.31.)

The regulations allow the licensee to make changes that are not potentially important to safety in radiation safety procedures and in equipment. When making changes, it is the licensee's responsibility to ensure that the result will be in accord with the regulations and license conditions. Any change must be reviewed for radiation safety considerations before it is approved.

You should consider the following before making an application for a license amendment or making changes. Not all the questions apply to all changes. There may be other questions you should consider before making changes.

General

1. Proposed changes should be fully explained.
2. Do not include unexplained acronyms, abbreviations, or undefined words.
3. Spell out measurement units such as millicurie, microcurie, and millirem per hour; use the abbreviations only in calculations or log sheets.
4. Identify, by name or office, who is responsible for doing each task.

Room Changes

1. Why is the change needed?
2. What materials, and how much of each, will be used in the room?
3. Can the room be secured in case of spills?
4. Can the room surfaces be cleaned?
5. Is the room adequately ventilated?
6. Does the room provide radiation shielding?
7. What are the anticipated doses each week in the room and in surrounding areas?
8. What are surrounding areas used for? What might they be used for in the future?
9. Can the old room be cleaned, surveyed, and released for unrestricted use?

Equipment Changes

1. Why is the change needed?
2. Was the equipment designed for the intended purpose?
3. For detection and measuring equipment:
   a. What is the lowest level of detection for the equipment?
   b. What is the level of detection required?
   c. Will the instrument be compromised by ambient radiations, light, temperature, humidity, or chemicals in the area?
   d. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?
4. For protection equipment:
   a. What level of protection does it provide?
   b. What is the required level of protection?
   c. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?

Procedure Changes

1. Why is the change needed?
2. What doses or dose rates apply to the individuals affected by the change?
3. For each step in the procedure, what things are likely to go wrong either because of equipment failure or human error?
4. What are the likely consequences of problems noted in Question 3?
5. What steps can be taken to mitigate the consequences noted in Question 4?

APPENDIX U: Recommended Support Equipment and Services

Depending on the type of use and the size of the program, you will need various types of equipment and services to support your radiation safety program.

The suggested list provided here does not include the many disposable or reusable items that are also necessary. Also, the list is not all-inclusive, and all items are not absolutely necessary.

Needs are divided to correspond to the subparts of Part 35 that describe different types of medical uses of byproduct material. While instrumentation overlaps among subparts, duplication is generally not necessary unless an instrument is to be dedicated to a single area of use or a single user. Descriptions of some of the items follow the list.

Subpart D

1. Radiation detection survey meter
2. Dose calibrator
3. Constancy check source
4. Sealed sources for dose calibrator accuracy test
5. Constancy check source for uptake, dilution, and excretion equipment
6. Leak-test service for sealed sources
7. Syringe shield
8. Personnel monitoring service
9. Survey meter calibration service
10. Vial shields
11. Personnel shields

Subpart E

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources
7. Syringe shield
8. Hot lab area monitor
9. Flood source for gamma cameras
10. PLES, bar, orthogonal-hole, or quadrant phantom for gamma cameras
11. Lead L-block
12. Fume hood
13. Radioactive aerosol and gas administration system and trap
14. Personnel monitoring service
15. Survey meter calibration service
16. Vial shields
17. Personnel shields

Subpart F

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources
7. Syringe shield
8. Fume hood
9. Personnel monitoring service
10. Survey meter calibration service
11. Vial shields
12. Personnel shields

Subpart G

1. Radiation detection survey meter

2.	Radiation measurement survey meter
3.	Lead L-block
4.	Remote handling tools
5.	Shielded transport cart
6.	Shielded storage safe
7.	Leak-test service for sealed sources
8.	Personnel monitoring service
9.	Survey meter calibration service
10.	Personnel shields

Note: If you are authorized for only a Sr-90 ophthalmic applicator, only a storage safe or built-in locked storage cabinet and leak-test service are necessary.

Subpart H

1. Secure storage area
2. Leak-test service for sealed sources
3. Radiation monitoring service for measuring dose rates from packages with replacement sources and decayed sources.

Subpart I

1.	Radiation measurement or radiation detection survey meter
2.	Room monitor
3.	Patient viewing system
4.	Leak-test service
5	Calibrated dosimetry system
6.	Spot-check dosimetry system
7.	Direct-reading pocket dosimeters
8.	Personnel monitoring service
9.	Teletherapy physicist service
10.	Survey meter calibration service

Descriptions

A radiation detection survey meter usually has a GM tube or NaI(Tl) crystal detector. The scale may be labeled in cpm or mR/hr. It is useful for detecting microcurie amounts of radioactivity and indicating approximate exposure levels. If it is calibrated in mR/hr, the most sensitive scale will probably have a full-scale deflection between 0.1 and 1.0 mR/hr. It can be used for measuring small amounts of

radioactivity if the user has measured its detection efficiency (cpm/dpm) for the radionuclide being measured.

A radiation measurement survey meter can actually measure mR/hr. The detector is an ionization chamber, which is usually much larger than a GM tube. The scale is labeled in mR/hr, and the most sensitive scale usually will have a full-scale deflection between 1 and 10 mR/hr.

The dose calibrator uses an ionization chamber or GM detectors to determine the amount of radiation given off by a syringe or vial containing radioactive material. The logic system within the calibrator can then calculate the amount of radioactivity in the sample. Most dose calibrators have a digital display with either a "select range" switch or an automatic range-switching circuit. The final display is in microcuries, millicuries, or curies. A dose calibrator can measure from a few microcuries to a few curies. It is not sensitive enough to measure contamination wipe samples.

A constancy check source is a sealed source with the date of manufacture, radioisotope, and approximate activity noted.

A dedicated check source is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The same source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

The sealed sources for dose calibrator accuracy are also sealed sources with the date of manufacture and radioisotope noted. However, the activity will be certified to within a few percent by the manufacturer. These need not be on hand if the dose calibrator accuracy test is done by a contract service.

The leak-test service may be done in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually a well-type NaI(Tl) crystal with a ratemeter is necessary to assay gamma-emitter leak-test wipes. To determine the efficiency of detection, a sealed source with the same radioisotope as the source being tested is used, but its activity should be between 0.1 and 10 microcuries. This activity will be certified by the manufacturer to an accuracy within a few percent.

The hot lab area monitor usually has a GM detector, and the scale may be labeled in cpm or mR/hr. It should be sufficiently sensitive to detect an unshielded patient dose left lying unshielded anywhere in the hot lab.

The flood source for gamma cameras may be either one that is sealed or one that is filled by the user. The sealed sources usually contain about 5 millicuries of Co-57. The sources that can be filled by the user usually have a removable screw in a port through which radioactive material can be injected each morning.

PLES, bar, orthogonal-hole, and quadrant phantoms are used to monitor geometric linearity and resolution capability in gamma cameras. This type of test should be run weekly according to the instructions supplied by the manufacturer or the instructions in Appendix E to this guide.

A fume hood should have an adjustable sash. It should be directly vented to the outside air. The face velocity should be approximately 100 linear feet per minute with the sash at its normal location. This should be measured with a velometer. If one is not available, hang a strip of tissue paper about 1 inch wide and 3 inches long from the bottom of the sash; at the proper face velocity, it will be gently deflected into the hood.

A teletherapy room monitor usually has a GM detector and either a scale labeled in mR/hr or annunciator lights indicating when the source is on and off. It must be installed so it can be easily seen when entering the teletherapy room. A backup power supply must be provided.

When used by teletherapy technicians, direct-reading or indirect-reading pocket dosimeters provide an immediate indication of personnel whole body exposure in case of an accidental exposure. These should be calibrated using the source and procedure used for calibrating survey meters.

Personnel shields are used to shield workers from radioactive patients. They may be mobile upright shields in the nuclear medicine clinic or a patient's room when a technician or nurse must stay beside a patient, or they may be lead sheets used to shield transporters from patients in wheelchairs.

APPENDIX V: Filing System

The purpose of a filing system is to allow for the quick access of records. The system should be constructed to allow a person who is not familiar with the system to use it with minimal training. If you have not established a system, the one described below may be helpful. In addition to NRC-licensed activities, it includes sections for State-licensed natural and accelerator-produced radioactive material programs, x-ray survey and maintenance reports that are sometimes maintained by the Radiation Safety Officer, and various safety committees.

The filing system described contains two parts: The first part includes Sections A and 0-9 for files that are small or occasionally accessed. The second part consists of five looseleaf notebooks used to file records that are large, frequently accessed, or easily filed in alphabetical or chronological order.

Section A -- Active Projects

Set up an individual file for each project, e.g., planning a new radioisotope lab or x-ray installation or a research project. Label each file with a short title. File chronologically with new material in front. For example:

Shielding calculations for new x-ray room
TLD project
Registration and travel to summer meeting

Section O -- Forms

Set up a file for master copies of the forms you use in your facility and a file for copies of each form. Label the files as indicated.

0.1	Masters
0.2	Personal Exposure Monitor Applications
0.3	Exposure History Request
0.4	Exposure History Report
0.5	Teletherapy Monthly Check
0.6	Nuclear Medicine Daily Survey
0.7	Survey Meter Calibration
0.8	Sink Disposal Logs
0.9	Vented Release Logs
0.10	Decay-In-Storage Release Records
0.11	Room Survey Master Forms
	etc.

Section 1 -- Committees

Each subsection of this section is devoted to a single committee. In some cases, the file will contain only meeting minutes. In other cases, the file may also include a committee charter, curricula vitae of members, and topical reports.

1.1	Radioactive Drug Research Committee
1.2	Hospital Safety Committee
1.3	Research Safety Committee
1.4	Research Review Committee
1.5	Radiation Safety Committee
	etc.

Section 2 -- NRC License

2.1	License Applications, License
2.2	Amendment Requests, Amendments
2.3	Photocopies of License
2.4	Records of Minor Changes
2.5	Inspection Reports and Replies
2.6	Visiting Authorized User Credentials
2.7	Misadministration Reports

2.8	Other Correspondence etc.

Section 3 -- Inventories, Surveys, and Waste

3.0	Inventory Summary Sheet
3.11	Nuclear Medicine Surveys and Inventory Summaries
3.12	Research Lab Surveys and Inventory Summaries
3.21	I-Therapy Room Release Surveys
3.22	Brachytherapy/Sealed Source Quarterly Inventory and Survey
3.23	Leak-Test Records
3.30	Room Survey Sets for Future Use
3.41	Annual Sink Disposal Summary
3.42	Annual Vent Disposal Summary
3.43	Hot Lab Sink Disposal Logs
3.44	Research Lab Sink Disposal Logs
3.45	Decay-In-Storage Release Logs etc.

Section 4 -- Contract Services

4.1	Personal Dosimetry Service Contract
4.2	Change Forms
4.3	Monthly Exposure Reports
4.4	Waste Shipment Contract
4.5	Transfers of Byproduct Material etc.

Section 5 -- Training Lecture Outlines, Handouts, and Attendance Logs

5.11	Nonradiology Physicians
5.12	Nonradiology Technologists
5.21	Radiology Physicians
5.22	Radiology Technologists
5.31	Administrators
5.32	Security

5.33	Physical Plant
5.34	Housekeeping
5.35	Animal Research Facility
5.41	Nursing--General Radiation Safety
5.42	Nursing for Brachytherapy
5.43	Nursing for Iodine Therapy
5.51	Brachytherapy Team
5.52	Diagnostic Nuclear Medicine Personnel
5.53	Therapeutic Nuclear Medicine Personnel
5.54	Teletherapy Personnel
5.61	In Vitro Users
	etc.

Section 6 -- Radiation Safety Equipment on Hand

Set up an individual file for each piece of equipment. The file should contain the user's manual, guarantee, service reports, and calibration reports. File alphabetically by manufacturer.

Section 7 -- Incidents

7.1	Personnel Exposures
7.2	Spills or Losses with No Personnel Exposure
7.3	Procedural Incidents

Section 8 -- State-Regulated Sources

8.1	X-ray Registration Sheets
8.2	NARM License Application, License

Set up an individual file for each piece of radiographic equipment. The file should contain the user's manual, guarantee, service reports, and inspection and calibration reports. File by room number. For portable x-ray machines, file by manufacturer's name or normal storage location.

Section 9 -- Facility Description

Set up files for blueprints, drawings, and permanently installed equipment such as incinerators, fume hoods, and walk-in boxes.

Loose-Leaf Notebooks

1. Dosimetry Service Monthly Packing Slips. Checkmark each name when the monitor is returned at the end of the monitor period. This will highlight persons who are not returning monitors promptly for processing.
2. Personnel Dosimetry Individual Applications. Behind each individual's application form, file copies of previous employment exposure, incidents, requests for previous employment exposure, and bioassay results.
3. Budget and Purchase Orders
4. NRC Regulatory Guides -- Divisions 8 and 10
5. Standard Operating Procedures
6. NRC Rules and Regulations

APPENDIX W: Bibliography

Title 10, Code of Federal Regulations[6]

Part 19 - Notices, Instructions, and Reports to Workers; Inspections
Part 20 - Standards for Protection Against Radiation
Part 21 - Reporting of Defects and Noncompliance
Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material
Part 31 - General Domestic Licenses for Byproduct Material
Part 32 - Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material
Part 33 - Specific Domestic Licenses of Broad Scope for Byproduct Material
Part 35 - Medical Use of Byproduct Material
Part 40 - Domestic Licensing of Source Material
Part 70 - Domestic Licensing of Special Nuclear Material
Part 71 - Packaging and Transportation of Radioactive Material
Part 170 - Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended

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APPENDIX X: Guidance on Complying With New Part 20 Requirements to Regulatory Guide 10.8, Revision 2,

(Draft was issued as DG-0002)

The revision of 10 CFR Part 20, "Standards for Protection Against Radiation" (ww 20.1001- 20.2401) changes a number of the requirements for medical use programs. The major change in the revised Part 20 is to incorporate newer national and international concepts on radiation protection, including the application of a risk-based approach to the establishment of radiation protection limits. Included are the adoption of the "effective dose" concept, specification of occupational dose limits as the sum of internal and external dose, and use of annual limits on intake (ALIs) and derived air concentrations (DACs) as a means for regulating the ingestion and inhalation of radionuclides. The adoption of the effective dose concept and the application of the occupational dose limit to the sum of the internal and external doses change the methodology to be used for evaluating, controlling, and recording radiation doses. In addition to the changes to the dose methodology, there are other differences between the provisions of 10 CFR 20.1-20.601 and the provisions of 10 CFR 20.1001-20.2401.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses or license renewals and for evaluating compliance with 10 CFR 20.1001-20.2401.

Regulatory Guide 10.8 was prepared under the provisions of 10 CFR 20.1-20.601 and 10 CFR Part 35. This new appendix discusses the major differences introduced by the revised 10 CFR Part 20 that modify the guidance previously provided by the NRC for the conduct of medical use programs.

Any information collection activities mentioned in this appendix are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014.

The following are the major areas of medical use programs affected by the revised Part 20.

1. RADIATION PROTECTION PROGRAMS

(See Appendix G to Regulatory Guide 10.8)

In the revised Part 20, 10 CFR 20.1101 requires each licensee to develop, document, and implement a radiation protection program appropriate to the scope and extent of the activities conducted and to review at least annually the program content and its implementation. Further, 10 CFR 20.1101 requires that each licensee use engineering controls and procedures to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). In addition, 10 CFR 20.2102 provides the recordkeeping requirements for radiation protection programs.

The requirements in 10 CFR 20.1101 are consistent with the requirements for control of occupational exposures in 10 CFR Parts 33 and 35. Radiation protection programs that have been established under the requirements of 10 CFR Parts 33 and 35 will be considered to be acceptable to meet the occupational ALARA requirements of the revised 10 CFR Part 20 when the program activities are limited to external occupational exposures. However, licensees who handle unsealed radioactive materials that may cause internal exposure to members of the public will need to supplement their ALARA programs to address potential internal as well as external doses to members of the general public from effluents to unrestricted areas. Additional guidance is being developed on this, and it will be addressed in a separate regulatory guide. Licensees should establish ALARA goals or objectives for effluents.

In developing an ALARA radiation protection program, licensees should design the program based on the size of the licensed facility, the potential hazards associated with radiation exposure, the potential intake of radioactive material, and the physical characteristics of the radionuclides (i.e., solid, liquid, or gas). For example, the magnitude of an ALARA program for a large research hospital would be expected to be considerably more comprehensive in scope than a radiation protection program for a private practice physician. The program should include the mechanisms for periodic (at least annually) review of performance, as well as actions to be taken when ALARA

goals or objectives are not met.

The revised 10 CFR Part 20 does not require that a numerical cost-benefit analysis (quantitative approach) be used to demonstrate ALARA. However, NRC encourages medical licensees to use quantitative analyses in developing ALARA programs and procedures. If it can be performed readily, licensees should demonstrate through quantitative analysis that the cost and benefits associated with design, engineering controls, and operating procedures have been optimized in accordance with the ALARA principle. If a quantitative analysis cannot be readily performed, licensees should thoroughly evaluate any design or engineering controls that may need to be changed to keep operating procedures ALARA.

Examples of the type of ALARA optimization considerations appropriate to the conduct of medical use programs are presented in the National Council on Radiation Protection and Measurement (NCRP) Report No. 107, "Implementation of the Principle of As Low As Is Reasonably Achievable (ALARA) for Medical and Dental Personnel,"[14] December 31, 1990. This NCRP report provides specific hypothetical examples of optimization decisions in implementing ALARA in nuclear medicine and radiation oncology.

2. INTERNAL DOSE METHODOLOGY

The revised 10 CFR Part 20 incorporates the new dose methodology system developed by the International Commission on Radiological Protection (ICRP), which specifies radiation dose limits in terms of an "equivalent" whole body dose, taken to be the sum of individual organ committed doses weighted by the risk of biological effect for each of the organs irradiated. This effective dose equivalent concept is used to control the stochastic biological effects of exposure to ionizing radiation. Nonstochastic, or threshold, biological effects are avoided by establishing dose limits for the committed dose received by an individual organ and for the exposure to the skin and to the lens of the eye (see 10 CFR 20.1201).

2.1 Units and Terms for Internal Exposure

The revised 10 CFR Part 20 uses the "special" units of dose and activity and presents the corresponding values for the international system (SI). Records and reports required under the revised Part 20 are to be maintained using the "special" units.

The following table provides the conversions between the two systems of measurement:

Special Units		
(Activity) curie (Ci)	=	3.7 x 10!) disintegrations per second (3.7 x 10!) Bq)
(Absorbed dose) rad	=	100 ergs/gram (0.01 Gy)
(Dose equivalent) rem	=	Quality factor x rad (0.01 Sv)
SI Units		
(Activity) becquerel (Bq)	=	1 disintegration per second (2.7 x 10-!! Ci)
(Absorbed dose) gray (Gy)	=	1 joule/kg (100 rads)

(Dose equivalent) sievert (Sv)	=	Quality factor x grays (100 rems)

In addition, the revised Part 20 introduces new terms for radionuclide intakes by means of inhalation and ingestion, e.g., derived air concentration (DAC). For a few radionuclides (e.g., noble gases such as xenon), the terms apply to exposures from submersion.

The new term DAC is used, in broad terms, similar to the way in which the maximum permissible concentration (MPC) is used in Appendix B, Table I, Column 1, to 10 CFR 20.1-20.601 and 20.103. Exposure to airborne radioactivity at a level of 1 DAC for 1 year (2000 hours) would result in either a committed effective dose equivalent of 5 rems (50 mSv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. In order to show compliance with the occupational dose limit of 5 rems (50 mSv), a facility must consider the contributions of internal and external doses prior to calculating ventilation and gas clearance time.

Appendix O to this Regulatory Guide 10.8 provides model procedures for calculating worker doses from concentrations of gases in work areas and for calculating spilled gas clearance times. The procedure states that the MPC values for the radionuclide of interest should be used in the calculations. To implement the revised Part 20, the DAC value for the radionuclide of interest, in conjunction with the contribution of external dose, must be used instead of the MPC value. For example, consider the following simplified approach to determining required ventilation rates in an area where xenon-133 procedures will be performed:

Example

A new room is being designed in an existing nuclear medicine department where xenon-133 ventilation studies will be performed. You are asked to calculate the minimum ventilation rates required to maintain compliance with the occupational dose limits.

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the DAC value for xenon-133 to allow for the estimated annual external exposure.

   A simplified method is to subtract the estimated external dose from the occupational dose limit of 5 rems (50 mSv) and divide this number by 5 rems. This yields the fraction of the dose limit of 5 rems that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in Appendix B to 10 CFR ww 20.1001-20.2401 in Table 1, Column 3.

   The annual external dose is 2 rems. The listed DAC value for xenon-133 is 1E-4 µCi/ml. The modified DAC value should be based on 3 rems that could still be incurred from internal exposure.

$$DAC\,(modified = \frac{5\,rems}{3\,rems} \times 1E\text{-}4m\ Ci/ml = 6E\text{-}5\ Ci/ml)$$

3. Calculate the minimum ventilation rates for the room using the procedure provided in Appendix O to this Regulatory Guide 10.8. In place of the MPC value stipulated in Appendix O, use the modified DAC value. In the example provided above, the modified DAC value (6E-5 µCi/ml) would be used instead of the MPC value for xenon-133.

The discussion and example presented in this section do not specifically address ALARA and the monitoring thresholds for internal doses as it relates to the summation of internal and external dose. However, it should be noted that modifications to ventilation rates can be a means to maintaining exposures ALARA. In addition, increased ventilation rates may negate the requirement to monitor internal dose and, as such, may eliminate the necessity to sum internal and external dose to show compliance with the occupational dose limits.

2.2 Occupational Dose Limits

In 10 CFR 20.101, the quarterly occupational dose limit of 1.25 rems (5 rems in a year) applies only to whole body exposures to external radiation (10 CFR 20.101). If the licensee has a dose history and a worker's cumulative dose is less than 5(age-18) rems, the worker could be allowed under certain circumstances to receive occupational exposure in excess of the 10 CFR 20.101(a) limit up to 3 rems per quarter (10 CFR 20.102(b)). In addition to the 5-rem annual total for occupational external exposure, 10 CFR 20.103 specifies a separate limit to apply to exposures to concentrations of radioactive materials in air in restricted areas (10 CFR 20.103 and Column 1, Table 1, of Appendix B to ww 20.1- 20.601).

The revised Part 20 applies the 5-rem (50-mSv) occupational dose limit as a whole body "effective" dose. This limit is the sum of the deep-dose equivalent from external sources and the committed effective dose equivalent to the organs exposed from the internal uptake of radionuclides, expressed as the total effective dose equivalent (10 CFR 20.1201). Additional guidance is provided in Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Doses," on the methods to be used for determining these dose equivalents. Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," provides guidance on reporting the dose data on NRC Forms 4 and 5. The revised Part 20 no longer contains provisions for an age proration 5(N-18).

2.3 Effective Dose Equivalent

The effective dose equivalent concept described above makes it possible to combine both the internal and external doses in assessing the overall risk of health effects to an individual. Prior to the revision of Part 20, the activity concentration limits for intakes of a single radionuclide (in Appendix B to ww 20.1- 20.601) were based on controlling the dose to the organ receiving the highest dose ("critical organ"). These concentration limits, however, were treated separately from the dose limits for external exposure. The revised 10 CFR Part 20 dose methodology evaluates the doses to all major body organs, multiplies these doses by the appropriate organ weighting factors, and then sums the organ-weighted doses to obtain a whole body risk-weighted "effective dose." The ALIs and DACs in Appendix B to ww 20.1001- 20.2401, therefore, reflect the doses to all principal organs that are irradiated, not just the one organ that receives the highest

dose, as was done previously.

3. DECLARED PREGNANT WOMEN [Embryo/Fetus Dose Limits]

(See 10 CFR 20.1003 and 20.1208)

The revised Part 20 uses the term "declared pregnant woman" to mean a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

For declared pregnant women, the NRC limits the dose to the embryo/fetus to 0.5 rem (5 mSv) over the entire pregnancy. In addition, the licensee is required to make an effort to avoid substantial variation above a uniform monthly exposure rate (0.05 rem/month) (0.5 mSv/month). Declared pregnant women are not allowed to receive planned special exposures that involve whole body doses or maternal intakes that could result in exceeding the embryo/fetus dose limit. The radiation protection program should make provisions for instructing women workers about the special need to protect the embryo/fetus and to encourage them to promptly notify their employer if they become pregnant. Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus," contains guidance on evaluating the dose to the embryo/fetus.

4. LEVELS IN UNRESTRICTED AREAS

(See 10 CFR 20.1301 and 20.1302)

The revised Part 20 uses the following terms with regard to areas with or without radiological restrictions:

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 mrem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

"Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted to 2 mrem (20 µSv) in any 1 hour from external sources and to 100 mrem (1 mSv) in a year total effective dose equivalent for individual members of the public. Depending on how the licensee's hospital areas are controlled and monitored, hallway areas outside patient therapy rooms and diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

5. NVLAP PROCESSORS

(See 10 CFR 20.1501)

Personnel dosimeters that require processing to determine the dose to compare to the 10 CFR Part 20 dose limits must be processed and evaluated by a dosimetry processor that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

6. CONTROL OF LABORATORIES

(See 10 CFR 20.1101, 20.1702, 20.1801, 20.1802, and 20.1902)

Access to laboratories using radionuclides, as well as the work practices in these laboratories, need to be controlled. Controlling access to radionuclide laboratories is accomplished by posting the entrance door and locking all accessible entrances to the laboratory when an authorized user, or an individual under the supervision of an authorized user, is not present. An acceptable alternative is to provide lockable storage facilities within the laboratory. In 10 CFR 20.1902(e), posting is required for each area or room in which there is used or stored a quantity of licensed material exceeding 10 times the quantity in Appendix C to ww 20.1001-20.2401. Some of the Appendix C quantities are changed. Appendix I to Revision 2 of Regulatory Guide 10.8 provides model rules for safe use of radiopharmaceuticals that can be used for radionuclide laboratories, and Appendix J provides model spill procedures.

7. POSTING AND CONTROLLING ACCESS TO PATIENT ROOMS

(See 10 CFR 20.1903(b))

When patients have received therapeutic administrations of radionuclides or therapeutic applications of sealed sources, the criteria for exceptions to posting requirements specified in 10 CFR 20.1903 will likely be exceeded. Dose rates from therapy patients can often exceed 5 mrem (50 µSv) per hour at 1 meter from the patient. Under these conditions, the entrance to the patient's room must be posted and access to the area controlled. Access can be controlled by routine surveillance and by posting instructions for hospital personnel and visitors at the entrance to the patient's room. Examples of such instructions can be found in Exhibit 17 of this Regulatory Guide 10.8. Systems such as remote TV surveillance, electronic eye, or personnel entry detection devices are considered acceptable for monitoring personnel access to the patient's room.

Note that 10 CFR 20.1903 allows exceptions to the posting requirements if specific conditions are met. Licensees should review 10 CFR 20.1902 and 1903 for posting requirements since some of the posting language has changed.

8. EXEMPTIONS TO LABELING REQUIREMENTS

(See 10 CFR 20.1905)

Licensees are not required to label containers holding licensed material in quantities less than the quantities listed in Appendix C to ww 20.1001- 20.2401. For iodine-125, carbon-14, and sulfur-35, the quantities below which labeling is not required are 1 µCi, 1000 µCi, and 100 µCi, respectively. In addition, licensees are not required to label containers holding licensed material in concentrations less than those specified in Table 3 of Appendix B to 20.1001-20.2401. For iodine-125, carbon-14, and sulfur-35, the exemption concentrations are 2 x 10-% µCi/ml, 3 x 10-$ µCi/ml, and 1 x 10-# µCi/ml, respectively.

9. PROCEDURES FOR RECEIVING AND OPENING PACKAGES

(See 10 CFR 20.1906(c) and 20.1906(d))

In the revised Part 20, 10 CFR 20.1906 modifies the Type A package quantity limits affecting package opening procedures, monitoring required for radioactive contamination on external surfaces of a package, and surface contamination levels requiring notification of the NRC as follows: Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 10 CFR 71.4 and Appendix A to Part 71 (e.g., more than 20 curies of molybdenum-99; 100 curies of technetium-99m; 10 curies of iodine-131, cesium-137, or iridium-192; or more than 70 curies of iodine-125). All shipping packages received, known to contain radioactive material, must be monitored for radioactive contamination and radiation levels if the package is labeled according to U.S. Department of Transportation rules (i.e., labeled with White I, Yellow II, or Yellow III) as containing radioactive material or if there is evidence of damage to the package. Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours, or within 3 hours from the beginning of the next working day if received after working hours, in accordance with the requirements of 10 CFR 20.1906. The NRC Regional Office and the final delivery carrier must be notified immediately if removable contamination exceeds the limits of 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47. Note that these Appendix X procedures for receiving and opening packages do not exempt packages containing less than Type A quantities of radioactive material from removable contamination surveys as does 10 CFR 20.205(b) and Appendix L to this Regulatory Guide 10.8. Therefore, it may be necessary for a licensee to revise current package opening procedures to reflect the changes in the revised Part 20.

10. EFFLUENT RELEASES TO SEWER

In the revised Part 20, 10 CFR 20.2003 allows licensees, under certain quantity release constraints, to discharge licensed material into sanitary sewers if the material is readily soluble in water or if the material is readily dispersible biological material. Dispersible in this context means able to be distributed as particles, more or less evenly throughout a medium, such as a sewer system. In practical terms, biological material should be divided finely enough so as to mix readily with a water stream and continue to disperse rather than to reconcentrate. This provision of the revised Part 20 allows continuation of the practice of discharging readily dispersible biological

materials such as ground-up animal carcasses. The prohibition of the discharge to sanitary sewer systems of nonbiological insoluble materials by w 20.2003 was designed to minimize the accumulation of insoluble material in the sewer system, treatment plant, and in sewage sludge. Licensees should note that the monthly average concentrations of radionuclides allowed to be released to sanitary sewers under 10 CFR 20.2003 and Table 3 of Appendix B to ww 20.1001-20.2401 are, generally, 10 times more restrictive than the monthly average concentrations that have been allowed to be released into sanitary sewer systems under 10 CFR 20.303(c). In addition, the licensee should note that there are no longer daily concentration limits for release of material to the sanitary sewer as discussed in Appendix R to this Regulatory Guide 10.8.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this Appendix X to Regulatory Guide 10.8. The regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this appendix and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988) is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC, as an enclosure to Part 20.

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VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed Revision 2 to Regulatory Guide 10.8 (Task FC 415-4) when the draft guide was published for public comment in August 1985. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task FC 415-4.

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1 If the applicant is a university with a' teaching hospital that operates under a separate annual budget and has been issued multiple licenses, the applicant should check the box that most closely approximates the annual operating budget of the entity that is the applicant, either the university or the teaching hospital.

2 Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for

possessing this material.

3 The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

4 Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

5 The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

6 Title 10 of the Code of Federal Regulations is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

7 NRC documents may be purchased from the U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082, or the National Technical Information Service, Springfield, VA 22161. Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131"

8 Draft regulatory guides may be obtained at no charge by writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Information Support Services.

9 IAEA reports may be obtained from UNIPUB, Inc., 345 Park Avenue South, New York, NY 10010.

10 ICRP reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523.

11 ICRU reports may be obtained from ICRU Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

12 NCRP reports may be obtained from NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

13 ANSI standards may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

14 NCRP reports can be purchased by writing to NCRP Publications, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814.